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## Description

The present invention relates to a connection component designed to be mounted on a tubing assembly for connecting the tubing assembly to a prefilled, foil-sealed container, and in particular to a connection component which includes a spike for penetrating the foil seal and an air vent having a flexible membrane therein. The present invention is also generally related to the subject matter of our EP-A-0281270 entitled "Vented Spike Connection Component".

In an enteral fluid delivery system for a patient, there is a need to provide a connecting component which will effect a quick connection of the fluid delivery set to a prefilled, foil-sealed container containing enteral fluid. In these fluid delivery systems, the connecting component is preferably a cap, which replaces the shipping cap on the prefilled container when the container is connected to the fluid delivery set for administration of the enteral fluid to the patient. The connecting component preferably includes a means for perforating the foil diaphragm on the container during attachment of the fluid delivery set to the container to simplify the assembly of the delivery system. It is further desirable that the connecting component provide a means to allow air to vent into the container as the enteral fluid flows from the container. This venting means should be designed to allow filtered air to flow into the container while preventing the air from flowing into and through the fluid passageway. Additionally, the venting means must prevent the passage of enteral fluid from the container through the air passageway.

One approach is illustrated in US-A-3,542,240, issued to Soloway on 24 November 1970. The first embodiment of Soloway illustrates the use of a single, centrally positioned projection designed to puncture the diaphragm of the container. The projection includes parallel air and liquid passageways therein to allow vented air to flow into the container while the fluid is administered to the patient. Additionally, Soloway illustrates the use of a check valve consisting of a steel ball and coil spring movably positioned within the air passageway. Finally, the Soloway device includes a circular flange on the bottle which engages a flexible sleeve on the cap to prevent the removal of the cap during the operation of the administration set. Another embodiment of Soloway illustrates the use of a pair of parallel, spaced apart air and liquid passageways therein.

The present invention seeks to provide a connection component for effecting a quick and reliable coupling between the fluid delivery set and the prefilled, sealed container. The present invention minimises the potential for contamination of

the container by providing an efficient means for puncturing the foil diaphragm of the container while simultaneously tearing the diaphragm to create a passageway therein to allow for the flow of vented filtered air therethrough.

According to the present invention there is provided a connecting component arranged for attachment to the opening of a fluid container, said connecting component including a circular body portion having a top surface, a bottom rim surface and a bottom inside surface for covering said container opening, a pointed projecting member) extending from said bottom inside surface toward said container at a position on said inside surface spaced apart from the centre of said circular body portion, a fluid channel passing through said body portion and said projecting member and wherein said fluid channel has a receiving opening therein and wherein said connecting component further includes an air passageway in said body portion spaced apart from said projecting member said air passageway including a one way valve characterised in that said valve includes a flexible member affixed to the bottom surface of the body portion for selectively allowing air to pass therethrough, and the body portion of said connection component includes a recess adjacent to said air passageway wherein said flexible member substantially overlaps said recess to resiliently block the flow of liquid from said container through said air passageway when the component is connected to said container.

An advantage of the present invention is that the connection component will puncture the protective diaphragm on the enteral fluid containing container as the connection component is being attached to the top of the container.

Another advantage of the present invention is that the air passageway is spaced apart from the liquid passageway to prevent the vented air from flowing into the liquid passageway.

Another advantage of the present invention is that the air passageway includes a flexible membrane therein to allow filtered air to flow into the enteral fluid container while preventing enteral fluid from leaking out of the container through the air passageway.

Another advantage of the present invention is that the spike member is offset from the centre of the cap so that as the cap is attached to the container, the spike member will tear the diaphragm to create a passageway therein for the vented air.

Another advantage of the present invention is that the opening of the air passageway is recessed from the diaphragm on the container to ensure that the diaphragm does not obstruct the flow of air from the air passageway.

The flexible member may be in a further recess on the bottom surface of the body portion. The flexible member may be attached to the body portion by a retainer which retains the flexible member on the bottom surface of the body portion.

The invention also includes a fluid delivery system consisting of a fluid containing container having a top opening, a pierceable protective diaphragm covering said opening and a connection neck for receiving a connection component thereon and a tubing set wherein the system includes a connection component as described herein.

#### Brief Description of the Drawings

Fig. 1 is an enlarged cross-sectional view of the connection component of the present invention; Fig. 2 is an enlarged cross-sectional view of the flexible disk and air passageway of the present invention shown in Fig. 1;

Fig. 3 is a top view of the foil diaphragm of the prefilled container after the diaphragm has been penetrated by the connection component of the present invention;

Fig. 4 is an exploded perspective view, partly in section taken along lines 4--4 of Fig. 6; Fig. 5 is a partial cut-away view illustrating the connection component attached to the container and tubing of the present invention; and

Fig. 6 is a bottom view of the connection component of the present invention.

Fig. 7 is a partial cut-away view illustrating the connection component piercing the foil diaphragm of the prefilled container.

#### Detailed Description of the Preferred Embodiment

One form of the present invention is illustrated in the drawings and is described generally herein as a connection component or cap 10. The cap 10 includes a top surface 12, a bottom inside surface 14 and a rim 16 adapted to be removably mounted on the neck 18 of a prefilled container 20. The cap 10 is preferably of a one-piece construction formed from a moulded plastic such as polystyrene.

The top surface 12 includes a pair of cylindrically shaped first and second members, 22 and 24, respectively, extending outwardly from the top surface 12 of the cap 10. Both members, 22 and 24, are offset from the central axis C1 of the cap 10, with the second member 24 being positioned midway between the central axis C1 of the cap 10 and one side of the cap 10, while the first member 22 is offset slightly from the central axis C1 of the cap 10. The first member 22 includes an internal liquid passageway 26 and is adapted to be attached to a plastic tubing 28 which, along with the cap 10, forms part of the fluid delivery set. The second member 24 includes an internal air passageway 30 and a standard filter (not shown) which

allows filtered air to flow into the prefilled container 20.

The bottom inner surface 14 of the cap 10 includes a spike member 32 which is formed by truncating the cylindrically shaped first member 22 at an angle starting at a location near the bottom inside surface 14 of the cap 10 and extending to an apex 34. The apex 34 of the spike member 32 extends beyond the bottom edge of the rim 16. The apex 34 is aligned on the bottom inside surface 14 of the cap 10 adjacent to the central axis C1 of the cap 10 while the opposing side 36 of the spike member 32 is positioned away from the central axis C1 of the cap 10 and in alignment with the apex 34 and central axis C1. The liquid passageway 26 in the first member 22 extends through spike member 32 to allow fluid communication between the tubing 28 and the container 20.

The bottom inside surface 14 of the cap 10 further includes first and second recesses, 42 and 44 (Fig.2) respectively, and a flexible disk 38. The first recess 42 extends along nearly the entire bottom inside surface 14 of the cap 10 to provide a spaced apart relationship between the bottom inside surface 14 of the cap 10 and the diaphragm 46 on the container 20. The second recess 44 is positioned generally between the apex 34 of the spike member 32 and the rim 16 of the cap 10. The air passageway 30 of the second member 24 opens into the second recess 44 between the centre of the second recess 44 and the rim 16 of the cap 10. The flexible disk 38 is retained in the second recess 44 by a spike shaped retainer 40. The retainer 40 is melted thermally or ultrasonically to retain the flexible disk 38 in the second recess 44. The flexible disk 38 is preferably constructed of a soft plastic or elastomeric, non-porous, material and is designed to overlap the rim of the second recess 44.

As illustrated in the drawings, the cap 10 has a central axis designated as C1, about which the cap 10 is rotated for attachment to the container 20. As further illustrated in the drawings, first and second members 22 and 24, respectively, are both offset from the central axis C1 and extend upwardly from the top surface 12 of the cap 10. Additionally, the apex 34 of spike member 32 on the bottom inside surface 14 of the cap 10 is oriented so that the opening of the liquid passageway 26 faces away from the opening of the second member 24. The centre of the liquid passageway 26 in the first member 22 is designated in the drawings as axis C2. Axis C2 of the liquid passageway 26 is offset from the central axis C1 by approximately 0.1 inch (2.5 mm). The centre of the air passageway 30 in the second member 24 is designated in the drawings as axis C3. Axis C3 of the air passageway 30 is offset from the axis C2 of the liquid passageway

26 by approximately 0.5 inch (12.7 mm). This aligned separation of the respective passageways, along with the orientation of the apex 34 on the spike member 32 effectively prevents air bubbles from flowing directly into the liquid passageway 26 of the first member 22.

With this preferred orientation of the spike member 32 and the first and second recesses, 42 and 44 respectively, of the present invention, air is drawn into the air passageway 30 of the second member 24 without significant obstruction by the diaphragm 46. As illustrated in Fig. 3, the diaphragm 46 is deformed and torn by the offset spike member 32 to provide an opening in the diaphragm 46 which is sufficiently extended to permit fluid to flow freely through the liquid passageway 26 in the first member 22 into the tubing 28 and to allow air to flow freely through the second member 24 into the container 20. The first recess 42 ensures that the flexible disk 38 will be spaced apart from the diaphragm 46 a sufficient distance so that the flexible disk 38 is allowed to flex in response to the passage of air from the air passageway 30 into the container 20. The second recess 44 causes the flexible disk 38 to be biased slightly towards the inside of the container 20 and ensures that the air bubbles are deflected away from the liquid passageway 26.

The cap 10 of the present invention forms an integral part of an improved fluid delivery set. The enteral fluid containing container 20 is typically delivered with a specially designed shipping cap which must be removed prior to the attachment of the cap 10 on the container 20. In the preferred embodiment, the cap 10 is threaded onto the neck 18 of the container 20. As the cap 10 is threaded onto the container 20, the spike member 32 pierces the protective diaphragm 46 in the manner illustrated in Fig. 3. Next, the tubing 28 is attached to the first member 22 on the top surface 12 of the cap 10. The container 20 is then inverted and the air is removed from the tubing 28. Finally, the safety cap 48 is removed from the second member 24 to allow the air passageway 30 to communicate through a filter (not shown) between the atmosphere and the interior of the container 20. The delivery set is now ready to administer the enteral fluid to the patient.

In operation, the enteral fluid flows from the container 20 through the liquid passageway 26 into the tubing 28. As this occurs, filtered air is drawn into the air passageway 30 through the second member 24. The air will flow through the air passageway 30 and bubble past the flexible disk 38. By extending the flexible disk 38 beyond the perimeter of the second recess 44, the flexible disk 38 operates as a flexible barrier against the bottom inside surface 14 of the cap 10 to direct the air

bubbles away from the opening of the liquid passageway 26 in the container 20. The flexible disk 38 also prevents the loss of enteral fluid from the container 20 through the air passageway 30 by pressing against the second recess 44 whenever the pressure inside the container 20 is greater than the atmospheric pressure.

The detailed description of the preferred embodiment of the invention having been set forth herein for the purpose of explaining the principles thereof, it is known that there may be modifications, variations or changes in the invention without departing from the proper scope of the invention as defined by the claims attached hereto.

## Claims

1. A connecting component (10) arranged for attachment to the opening of a fluid container (20), said connecting component (10) including a circular body portion having a top surface (12), a bottom rim surface (16) and a bottom inside surface (14) for covering said container opening, a pointed projecting member (32) extending from said bottom inside surface (14) toward said container (20) at a position on said inside surface spaced apart from the centre of said circular body portion, a fluid channel (26) passing through said body portion and said projecting member (32) and wherein said fluid channel (26) has a fluid receiving opening therein and wherein said connecting component further includes an air passageway (30) in said body portion spaced apart from said projecting member said air passageway including a one way valve characterised in that said valve includes a flexible member (38) affixed to the bottom surface (14) of the body portion for selectively allowing air to pass therethrough, and the body portion of said connection component (10) includes a recess (44) adjacent to said air passageway (30) wherein said flexible member (38) substantially overlaps said recess (44) to resiliently block the flow of liquid from said container (20) through said air passageway when the component (10) is connected to said container (20).
2. A connecting component as claimed in Claim 1, wherein the flexible member (38) is in a further recess (42) on the bottom surface (14) of said body portion.
3. A connecting component, as claimed in Claim 1 or 2 wherein the flexible member (38) is attached to said body portion by a retainer (40) which retains said flexible member on the bottom surface (14) of said body portion.

4. A fluid delivery system consisting of a fluid containing container (20) having a top opening, a pierceable protective diaphragm (46) covering said opening and a connection neck for receiving a connection component (10) thereon and a tubing set, characterised in that the connection component corresponds to that claimed in any one of Claims 1 - 3.
5. A fluid delivery system as claimed in Claim 4 wherein the body of said connection component (10) includes the further recess (42) therein to space said flexible member apart from said diaphragm when said cap shaped member is attached to said container.

#### Patentansprüche

1. Verbindungsmittel (10), das an der Öffnung eines Flüssigkeitsbehälters (20) befestigbar ist, wobei das Verbindungsmittel (10) einen kreisförmigen Körperabschnitt umfaßt, der eine Oberfläche (12), eine untere Randfläche (16) und eine innere Bodenfläche (14) zur Abdeckung der Behälteröffnung aufweist, wobei sich ein spitzes, vorspringendes Teil (32) von der inneren Bodenfläche (14) in Richtung Behälter (20) an einer Stelle der Innenfläche erstreckt, die vom Zentrum des kreisförmigen Körperabschnitts beabstandet ist, und ein Flüssigkeitskanal (26) vorgesehen ist, der durch den Körperabschnitt und das vorspringende Teil (32) führt, und wobei der Flüssigkeitskanal (26) eine Öffnung zur Aufnahme der Flüssigkeit aufweist und wobei das Verbindungsmittel außerdem einen von dem vorspringenden Teil beabstandeten Luftdurchlaß (30) in dem Körperabschnitt aufweist, wobei der Luftdurchlaß ein Einweg-Ventil umfaßt, dadurch gekennzeichnet, daß das Ventil ein an der Bodenfläche (14) des Körperabschnitts befestigtes flexibles Teil (38) zum selektiven Durchlaß von Luft umfaßt, und der Körperabschnitt des Verbindungsmittels (10) eine Ausnehmung (44) neben dem Luftdurchlaß (30) aufweist, wobei das flexible Teil (38) die Ausnehmung (44) beträchtlich überlappt, um federnd den Flüssigkeitsstrom aus dem Behälter (20) durch den Luftdurchlaß zu verhindern, wenn das Verbindungsmittel (10) mit dem Behälter (20) verbunden ist.
2. Verbindungsmittel gemäß Anspruch 1, worin das flexible Teil (38) in einer weiteren Ausnehmung (42) an der Bodenfläche (14) des Körperabschnitts angeordnet ist.
3. Verbindungsmittel gemäß Anspruch 1 oder 2, worin das flexible Teil (38) mit einem Halter

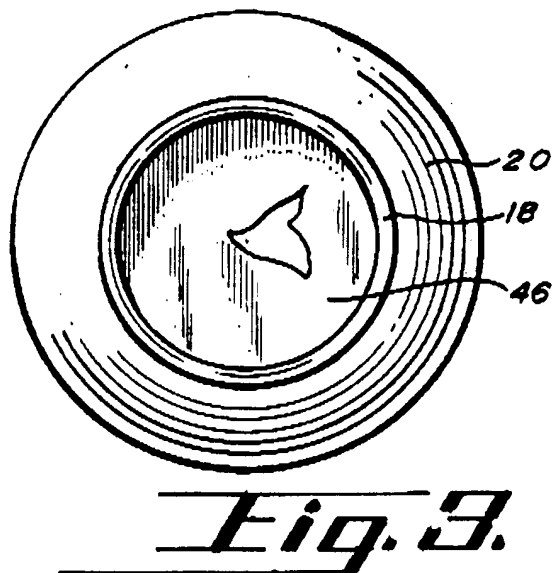
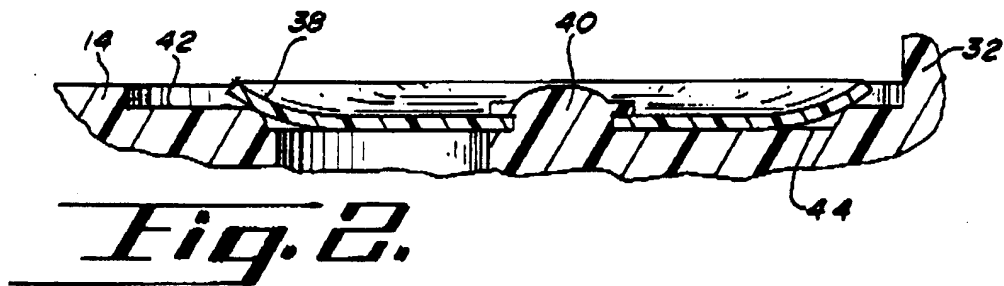
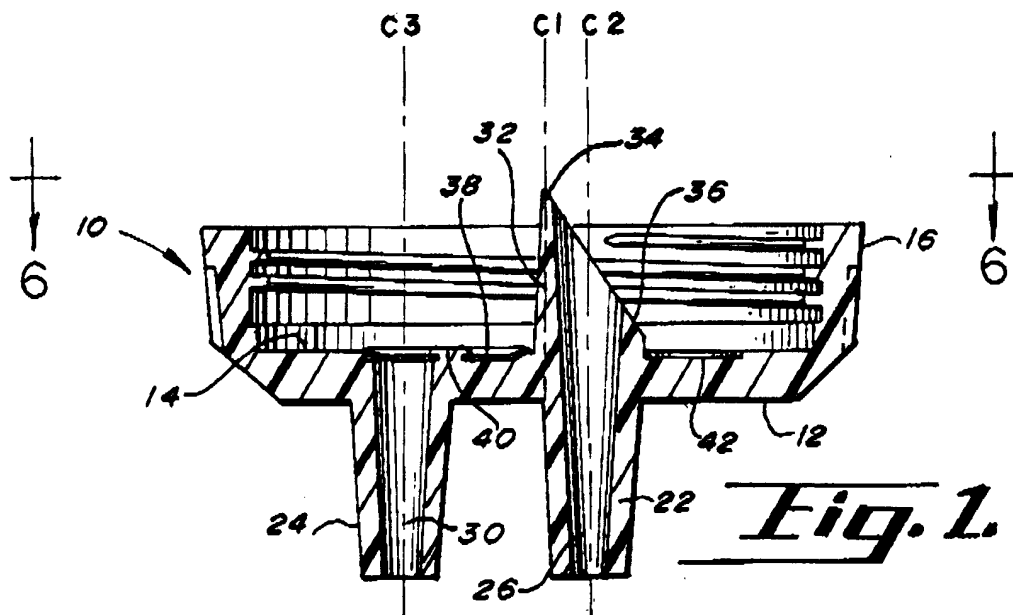
(40) an dem Körperabschnitt befestigt ist, wobei der Halter das flexible Teil an der Bodenfläche (14) des Körperabschnitts hält.

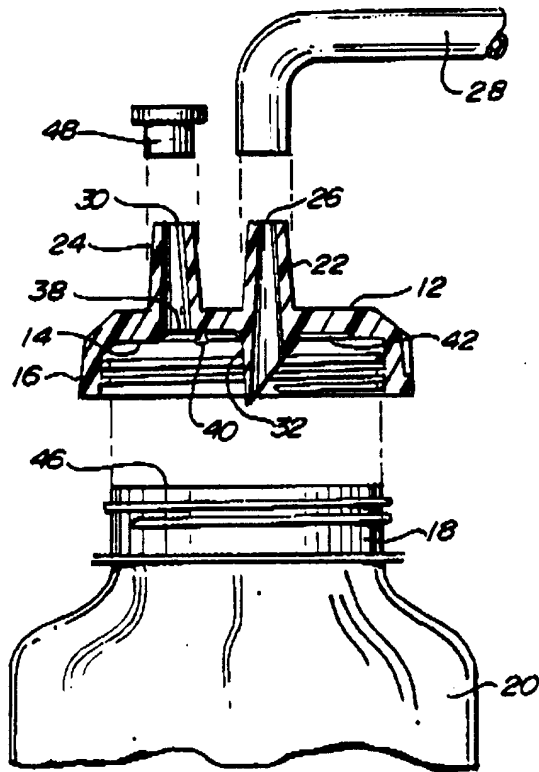
4. Abgabevorrichtung für Flüssigkeiten, bestehend aus einem Behälter (20) mit Flüssigkeit, der eine obere Öffnung, eine durchstechbare Schutzmembran (46), welche die Öffnung bedeckt, und einen Anschlußhals zur Aufnahme eines Verbindungsmittels (10) und eine Schlauchanordnung aufweist, dadurch gekennzeichnet, daß das Verbindungsmittel ein Verbindungsmittel gemäß einem der Ansprüche 1 - 3 ist.
5. Abgabevorrichtung für Flüssigkeiten gemäß Anspruch 4, worin der Körper des Verbindungsmittels (10) die zusätzliche Ausnehmung (42) aufweist, damit das flexible Teil von der Membran beabstandet ist, wenn das deckelförmige Teil an dem Behälter befestigt ist.

#### Revendications

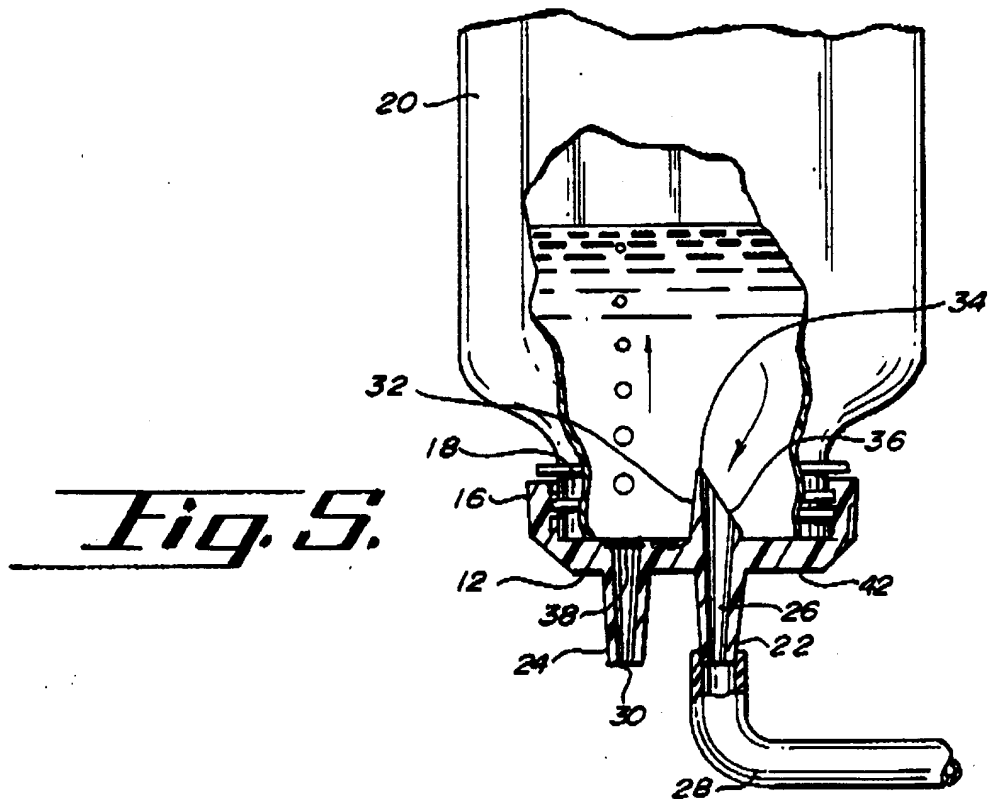
1. Élément de raccordement (10) conçu pour être fixé à l'orifice d'un récipient (20) de liquide, cet élément (10) comprenant un corps circulaire comportant une surface supérieure (12), une surface de couronne inférieure (16) et une surface intérieure inférieure (14) pour couvrir l'orifice du récipient, un élément saillant pointu (32) qui part de cette surface intérieure inférieure (14) et s'étend vers le récipient (20), à un endroit sur ladite surface intérieure, qui est espacé du centre du corps circulaire, un passage de liquide (26) traversant le corps et l'élément saillant (32), le passage de liquide (26) présentant une ouverture de réception du liquide et l'élément de raccordement comprenant, en outre, un passage d'air (30) dans le corps, espacé de l'élément saillant, ledit passage d'air comprenant un clapet antiretour, caractérisé en ce que le clapet comprend un élément souple (38) fixé à la surface inférieure (14) du corps pour permettre de façon sélective à l'air de passer, et le corps de l'élément de raccordement (10) présente un évidement (44) à proximité du passage d'air (30) dans lequel l'élément souple (38) recouvre sensiblement l'évidement (44) pour arrêter élastiquement le passage du liquide provenant du récipient (20) par le passage d'air quand l'élément (10) est raccordé au récipient (20).
2. Élément de raccordement suivant la revendication 1, dans lequel l'élément souple (38) se trouve dans un évidement supplémentaire (42) sur la surface inférieure (14) du corps.

3. Elément de raccordement suivant la revendication 1 ou 2, dans lequel l'élément souple (38) est fixé au corps par un élément de retenue (40) qui retient l'élément souple sur la surface inférieure (14) du corps. 5
4. Système de fourniture de liquide constitué par un récipient (20) contenant du liquide, présentant un orifice supérieur, un diaphragme protecteur (46), pouvant être percé, couvrant cet orifice et un col de raccordement destiné à recevoir un élément de raccordement (10) et un ensemble de tubes, caractérisé en ce que l'élément de raccordement correspond à celui qui est revendiqué dans l'une quelconque des revendications 1 à 3. 10 15
5. Système de fourniture de liquide suivant la revendication 4, dans lequel le corps de l'élément de raccordement (10) comprend l'évidement supplémentaire (42) pour espacer l'élément souple du diaphragme quand l'élément en forme de bouchon est fixé au récipient. 20 25 30 35 40 45 50 55 6





*Fig. 4.*



*Fig. 5.*



